

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
19 August 2004 (19.08.2004)

PCT

(10) International Publication Number  
**WO 2004/069224 A3**

- (51) International Patent Classification<sup>7</sup>: **A61K 9/127**, 31/337
- (21) International Application Number: **PCT/US2004/003157**
- (22) International Filing Date: 3 February 2004 (03.02.2004)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
60/444,958 3 February 2003 (03.02.2003) US
- (71) Applicant (for all designated States except US):  
**NEOPHARM, INC.** [US/US]; 150 Field Drive, Suite 195,  
Lake Forest, IL 60045 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **ZHANG, Jia-Ai** [US/US]; 1251 Maidstone, Vernon Hills, IL 60061 (US). **UGWU, Sydney** [NG/US]; 4005 Stoney Island, Gurnee, IL 60031 (US). **MA, Lan** [CN/US]; 7606 Cascade Way, Gurnee, IL 60031 (US). **ANYARAMBHATLA, Gopal** [IN/US]; 1014 Lakehurst Dr., Apt. 104, Waukegan, IL 60083 (US). **AHMAD, Imran** [US/US]; 4731 Pebble Beach Drive, Wadsworth, IL 60083 (US).
- (74) Agents: **HEFNER, M., Daniel et al.**; Leydig, Voit & Mayer, Ltd., Two Prudential Plaza, Suite 4900, 180 N. Stetson Avenue, Chicago, IL 60601-6780 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**  
— with international search report  
— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the International search report:  
11 November 2004
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



**WO 2004/069224 A3**

(54) Title: STABLE STERILE FILTERABLE LIPOSOMAL ENCAPSULATED TAXANE AND OTHER ANTINEOPLASTIC DRUGS

(57) Abstract: The invention provides a formulation of one or more antineoplastic drugs encapsulated in liposomes including at least a lipid fraction in addition to the antineoplastic drug, wherein the composition is stable in an aqueous solution at room temperature.

# INTERNATIONAL SEARCH REPORT

national Application No

701/US2004/003157

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61K9/127 A61K31/337

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 93/18751 A (UNIV GEORGETOWN) 30 September 1993 (1993-09-30) examples 1-4 claims	1-26
X	& US 5 648 090 A (RAFAELOFF RAFAEL ET AL) 15 July 1997 (1997-07-15) cited in the application	1-26
X	& US 5 424 073 A (HUSAIN SYED R ET AL) 13 June 1995 (1995-06-13) cited in the application	1-26
X	WO 95/13053 A (UNIV NEW YORK) 18 May 1995 (1995-05-18) page 5, line 1 - page 6, line 8 examples claims	1-26

-/--

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principles or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*&\* document member of the same patent family

Date of the actual completion of the International search

8 September 2004

Date of mailing of the International search report

16/09/2004

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Epskamp, S

## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US2004/003157

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	SHARMA A ET AL: "NOVEL TAXOL FORMULATIONS: PREPARATION AND CHARACTERIZATION OF TAXOL-CONTAINING LIPOSOMES" PHARMACEUTICAL RESEARCH, NEW YORK, NY, US, vol. 11, no. 6, June 1994 (1994-06), pages 889-896, XP000874406 ISSN: 0724-8741 page 891, left-hand column, paragraph 4; figure 1B page 892, left-hand column, paragraph 1; figures 3B,3C	1-26
X	WO 00/01366 A (NEOPHARM ; RAHMAN AQUILAR (US)) 13 January 2000 (2000-01-13) example 1	1-26

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2004/003157

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9318751	A	30-09-1993	AT 194767 T AU 3922193 A CA 2132711 A1 DE 69329073 D1 DE 69329073 T2 DK 706373 T3 EP 0706373 A1 ES 2148223 T3 GR 3034024 T3 PT 706373 T WO 9318751 A1 US 5424073 A US 5648090 A	15-08-2000 21-10-1993 30-09-1993 24-08-2000 18-01-2001 18-09-2000 17-04-1996 16-10-2000 30-11-2000 30-11-2000 30-09-1993 13-06-1995 15-07-1997
US 5648090	A	15-07-1997	US 5424073 A AT 194767 T AU 3922193 A CA 2132711 A1 DE 69329073 D1 DE 69329073 T2 DK 706373 T3 EP 0706373 A1 ES 2148223 T3 GR 3034024 T3 PT 706373 T WO 9318751 A1	13-06-1995 15-08-2000 21-10-1993 30-09-1993 24-08-2000 18-01-2001 18-09-2000 17-04-1996 16-10-2000 30-11-2000 30-11-2000 30-09-1993
US 5424073	A	13-06-1995	US 5648090 A AT 194767 T AU 3922193 A CA 2132711 A1 DE 69329073 D1 DE 69329073 T2 DK 706373 T3 EP 0706373 A1 ES 2148223 T3 GR 3034024 T3 PT 706373 T WO 9318751 A1	15-07-1997 15-08-2000 21-10-1993 30-09-1993 24-08-2000 18-01-2001 18-09-2000 17-04-1996 16-10-2000 30-11-2000 30-11-2000 30-09-1993
WO 9513053	A	18-05-1995	US 5415869 A AU 1176995 A CA 2153326 A1 DE 69425879 D1 DE 69425879 T2 EP 0683664 A1 JP 8508046 T WO 9513053 A1	16-05-1995 29-05-1995 18-05-1995 19-10-2000 08-02-2001 29-11-1995 27-08-1996 18-05-1995
WO 0001366	A	13-01-2000	US 6146659 A AU 730599 B2 AU 5088099 A BR 9906581 A CA 2301057 A1 CN 1275076 T EA 3678 B1 EP 1009384 A1 HU 0004583 A2	14-11-2000 08-03-2001 24-01-2000 26-09-2000 13-01-2000 29-11-2000 28-08-2003 21-06-2000 28-08-2001

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

T/US2004/003157

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0001366	A	JP 2001524990 T	04-12-2001
		JP 2004059590 A	26-02-2004
		NO 20001012 A	15-03-2000
		PL 338951 A1	04-12-2000
		SK 4642000 A3	07-11-2000
		TR 200000576 T1	21-11-2000
		WO 0001366 A1	13-01-2000
		US 2003035830 A1	20-02-2003
<hr/>			